DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Kobold, LLC
% Ms. Kathy Arpin
Regulatory Specialist
23403 E. Mission Avenue, Suite 220E
LIBERTY LAKE WA 99019

April 9, 2015

Re: K142330
Trade/Device Name: Kobold Ring and Tandem Applicator Set
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote Controlled Radionuclide Applicator System
Regulatory Class: II
Product Code: JAQ
Dated: March 27, 2015
Received: April 1, 2015

Dear Ms. Arpin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142330

Device Name
Kobold Ring and Tandem Applicator Set

Indications for Use *(Describe)*
The CT Compatible / MR Unsafe HDR Kobold Ring and Tandem Applicator Set is indicated for use in any case where high dose rate (HDR) radiation treatment of the cervix and uterus is accepted by up-to-date clinical guidelines.

The Kobold Ring and Tandem Applicator Set is intended for continuous use of up to 24 hours of contact with patient.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is furnished in accordance with requirements detailed in 21 CFR 807.92.

1.
The assigned 510(k) number is K142330

Submitter's Identification:

Kobold, LLC
23403 E. Mission Ave., Suite 220E
Liberty Lake, WA 99019

Correspondence:

Kathy Arpin
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Email: kathy.arpin@koboldmedical.com

Date of submission: August 14, 2014

2.
Device name

Kobold Ring Type Applicator Set
Proprietary name: Kobold Ring and Tandem Applicator Set™

A. Regulation Section: 892.5700
B. Classification: Class II
C. Product Code: JAQ
D. Panel: Radiology

3.
Intended Use

The CT Compatible / MR Unsafe HDR Kobold Ring and Tandem Applicator Set is indicated for use in any case where high dose rate (HDR) radiation treatment of the cervix and uterus is accepted by up-to-date clinical guidelines.

The Kobold Ring and Tandem Applicator Set is intended for continuous use of up to 24 hours of contact with patient.

4.

Device Description

The CT Compatible / MR Unsafe HDR Kobold Ring and Tandem Applicator Set™ design is based on the modified conventional Ring/Tandem applicator with a click fit connector interface. This applicator is particularly useful in providing an HDR radiation boost to the cervix and parametrical tissues in conjunction with external beam radiation therapy. The applicator consists of precision manufactured intrauterine rings, ring caps, and tandems, interlocking via a ring bracket. All components are designed for a defined geometry. The rings are provided in three different angles (30 degrees, 45 degrees, and 60 degrees) with three different tandem lengths (20 mm, 40 mm, and 60 mm from the ring axis) provided for each ring angle. Two ring caps are provided (5.0 mm and 7.0 mm).

5.

Substantial Equivalence Information

Information presented supports substantial equivalence of the CT Compatible / MR Unsafe HDR Kobold Ring and Tandem Applicator Set™ to the predicate device. The proposed device has similar indications for use, similar nature of body contact, is similar in shape and design, has the same fundamental technology and uses the same sterilization procedures. Please see predicate device brochures in **Appendix C**.

A. Predicate device name: Kobold Fletcher Type Applicator Set; Kobold Henschke Type Applicator Set
B. Predicate device K number: 123912
C. Comparison with predicate:

SUBSTANTIAL EQUIVALENCE TABLE	KOBOLD, LLC	KOBOLD, LLC
K-Number	K-142330	K-123912
Device Description	Applicator Set, Ring Type	Applicator Set, Henschke Type; Applicator Set, Fletcher Type
Indications for Use	The CT Compatible / MR Unsafe HDR Kobold Ring and Tandem Applicator Set is indicated for use in any case where high dose rate (HDR) radiation treatment of the cervix and uterus is accepted by up-to-date clinical guidelines. The Kobold Ring and Tandem Applicator Set is intended for continuous use of up to 24 hours of contact with patient.	The CT/MRI Compatible HDR Henschke Type Applicator and Fletcher Type Applicator are indicated for use in any case where high dose rate (HDR) radiation treatment of the cervix and uterus is accepted by up-to-date clinical guidelines.

Afterloader Compatibility	GammaMed®, VariSource® with click-fit connector	GammaMed®, VariSource® with click-fit connector
Design Geometry	Defined	Flexible
Materials	Titanium, Ultem®, Stainless Steel, Silicone, High Temperature Vinyl	Titanium, Ultem®, Stainless Steel, Silicone, High Temperature Vinyl
Packing	Tray	Tray
Sterility	Provided Non-Sterile	Provided Non-Sterile
Sterilization Methods, Sterilization Conditions	Steam 18 min at 273ºF (134ºC), 44psi (3 bar) Dry 15 min; no Sterrad® compatibility documented	Steam 18 min at 273ºF (134ºC), 44psi (3 bar) Dry 15 min; no Sterrad® compatibility documented
Biocompatibility	Documented	Documented
Anatomical Sites	Uterus, Cervix	Uterus, Cervix
Environmental Compatibility	CT Compatible/MR Unsafe	CT/MRI Compatible

6.

Test Principle, Performance Characteristics

The FDA has not established special controls or performance standards for this device.

7.

Bench Testing

Extensive testing in accordance with known standards is documented by the manufacturer for predicate device K123912. The standard is a specification for the materials used in surgical implant applications and predicate brachytherapy devices and for manufacturer's acceptance procedures for predicate device as provided in **Appendix A**.

8.

Conclusions

The Kobold Ring Type Applicator Set is similar in intended use and technological characteristics to predicate device reviewed. The device is similar with respect to indications for use and physical characteristics to predicate device in terms of section 510(k) substantial equivalency.

Contraindications: As per clinical guidelines and standard clinical practice.

Warnings and Precautions: The precautions and warnings are provided in the device labeling for the Kobold Ring and Tandem Applicator Set™.

9.
Summary

Description	Comparison with Predicate Device
Biocompatibility	Safe as Predicate Device
Performance Characteristics	Substantially equivalent
Intended Use	Substantially equivalent
Performance Tests	Not Required

Based on the information submitted in this 510(k) application, the Kobold Ring and Tandem Applicator Set™ has been demonstrated to be substantially equivalent to the predicate device.